K012439

FEB 0 6 2002

EXHIBIT 2

Radco Data AB
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SWEDEN
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Contact: Anders Berggren, President and CEO
July 30, 2001

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "DentalEye 2" Dental Image Management System
   Classification Name: 90 LLZ
   Common/Usual Name: Dental Image Management System

2. Equivalent legally marketed device: This product is similar in design and identical in function to the TAU TigerView, K955237
3. Indications for Use (intended use): Indicated for acquisition, storage, display, and manipulation of Dental Images
4. Description of the device: Intended uses in the dental industry include the following:
   Acquiring and handling of radiographs and color images:
   Viewing and manipulation for insurance claims adjudication·
   Viewing and manipulation for diagnostic purposes
   Viewing for patient education and consultation including cosmetic imaging.
   When used for diagnostic purposes, the patient population will be the general public, and the diseases/conditions that the device will be used to diagnose are: dental caries, periodontal disease and bone loss, tooth fractures, jaw misalignment, and other diseases and conditions that are encountered by general practitioners and specialists in the dental care field.
5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	TAU TigerView, K955237	"DentalEye 2" Dental Image Management System
Indications for use	Indicated for acquisition, storage, display, and manipulation of Dental Images	SAME
Host platform	Standard PC platform with Windows NT	SAME, can also use Windows 95, 98, and 2000
Video capture	Matrox Meteor II	Studio PCTV
Receive images from other systems	YES	SAME

6. Testing information and Conclusion
   In all material respects, the "DentalEye 2" Dental Image Management System is substantially equivalent to TAU TigerView, K955237. Testing was performed according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

DentalEye AB
% Mr. Daniel Kamm P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K012439
Trade/Device Name: DentalEye 2, Dental Image Management System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: December 11, 2001
Received: December 12, 2001

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number_____
Intended Uses for DentalEye 2 in the dental industry are as follows

Acquiring and handling of dental radiographs and color images
Viewing and manipulation for insurance claims adjudication.
Viewing and manipulation for diagnostic purposes
Viewing for patient education and consultation including cosmetic imaging.

_____ _____ _____ _____ _____ _____ _____ _____ _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1 OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012439